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May 18, 2007

David Schwartz, MD

Director

National Institute for Environmental Health Sciences

National Institutes of Health

P.O. Box 12233

Research Triangle Park, NC 27709

Dear Dr. Schwartz:

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, has serious concerns regarding the proposed restructuring of the Centers for Children's Environmental Health and Disease Research (Children's Centers), as proposed by the review panel report released on April 6, 2007.

Since their establishment in 1998, the Children's Centers have provided a vital forum for innovative, multidisciplinary research into key children's environmental health topics. Funded by the National Institute for Environmental Health Sciences (NIEHS) and the Environmental Protection Agency (EPA), the Children's Centers have fused basic and translational research to produce studies that are equally relevant to scientists, practicing pediatricians, and policymakers. As the report acknowledges, the Children's Centers have produced a range of successful studies and interventions, and this important aspect of children's health research must continue to be supported.

The AAP appreciates the continued commitment of both NIEHS and EPA to children's environmental health research. Children are uniquely susceptible to environmental influences, ranging from the impact of drugs or chemicals in utero to exposure to secondhand smoke or pesticides in the home. Moreover, many adult diseases begin in childhood and are caused or influenced by environmental factors. Research in children's environmental health is a wise investment that yields substantial returns.

The AAP appreciates the thoughtful review of the Children's Centers conducted by the panel. A number of important suggestions were made for improving the future works of the Centers. The AAP supports encouraging the use of epigenetics to examine gene-environment interactions, and urges that the Centers also consider how such information will be used and perceived by individuals and translated into improved health. The establishment of cohorts with particular exposure patterns strengthens research within Centers. Such cohorts may be a key to unraveling the consequences of environmental exposures. Working with and sustaining longitudinal cohorts requires time and money, however, and there is a need to address the subjects' motivation to sustain their participation. Epigenetics may be seen as a particular threat to vulnerable populations,

and working with the community is an important part of engaging and sustaining their participation. The report makes important recommendations in each of these areas that have the potential to enhance the Children's Centers program.

The AAP is concerned, however, that a number of the changes proposed for the Children's Centers would appear to weaken significantly those very areas cited as strengths of the program. The AAP urges you to reconsider the following issues before making any final decisions regarding the future structure and focus of the Children's Centers.

A Focus on Health Outcomes Is Warranted

The AAP believes that the panel fell short in achieving its goal of developing “a model that would allow the *basic science...to form the foundation for the overall research program* while also retaining research that emphasizes a *direct linkage to child health.*” The review panel cited the “limited number of health outcomes considered” as a weakness of the Children's Centers and listed as its first recommendation “strengthening the role of basic science in formulating research questions.” While basic science should certainly help to inform the research process, the AAP believes that specific health outcomes should be the clear, ultimate focus of the program. The Children's Centers were not and should not be refocused solely on basic research, but rather the pursuit of research that will lead directly to improvements in children's health. This approach would also appear to be consistent with the National Institutes of Health Roadmap, the mission of which is to “accelerate fundamental discovery and translation of that knowledge into effective prevention strategies and new treatments.”

Shifting to Investigator-Initiated Research May Shut Out Many PEH Researchers

One of the great benefits of the Children's Centers program has been its ability to fund and foster the nascent field of pediatric environmental health (PEH) science. However, that field remains the purview of only a handful of committed MD and PhD researchers. Two of the proposed changes to the Centers structure could have a detrimental effect on efforts to build the PEH field.

The AAP is concerned about the possible implications of the recommended shift in Center structure from Core and Research Project (P01) funding to Core and Investigator-Initiated Funded Grants (such as R01 and R21). This change should be accompanied by implementation of processes or systems to foster the continuation of a needed child-focused environmental health research agenda. Such processes may include requests for proposals that center on questions most relevant to children or by assigning priority to research on such issues. Special review panels may be needed, depending upon the topic focus.

Similarly, the review report cites “transdisciplinary research” and “training of future researchers” as major strengths of the Children's Centers but then proceeds to propose eliminating the focus on both of these areas. The recommended structure makes both training and the new investigator program “optional,” meaning that they will be of secondary importance for Centers in designing and competing for the program. The AAP recommends maintaining a strong focus on both transdisciplinary training and the development of new investigators in the Children's Center program.

Selection of Sites and Awardees Must Be Consistent

The review panel issued a set of seemingly conflicting recommendations regarding the selection of Children's Centers. While the authors stated that "limited geographic representation" is a weakness of the program, they emphasize the importance of identifying the most talented scientists. Yet they also emphasize the importance of identifying the best applicants, an approach that may produce geographic limitations. The AAP suggests that the limited geographic representation could be a function of the limited funding of the program, which could be addressed effectively by increasing the resources available at the NIH overall and for this program in particular to establish additional Centers.

Research Generated Must Be Relevant to Policymakers

The Children's Centers have served a vital function in producing work that allows EPA to translate research into public policy. The report acknowledges the main areas in which Children's Center research has led directly to changes in laws and regulations, including EPA directives on pesticides, changes to New York City bus fleet and ports, and reversing the World Health Organization decision on DDT. The AAP believes the current Children's Research Center model works best for EPA and other policymakers in terms of providing information useful in setting policy (i.e., facilitating access to vulnerable populations, including community outreach, providing an infrastructure to respond to emerging risk issues).

Community Outreach and Participation Is Critical

The review panel identified "successful community outreach" as a key strength of the Children's Centers. However, they proposed revisions to the Center structure to make the previous requirement for community-based participatory outreach to be "optional." While the AAP agrees that this particular strategy of community directed research may be optional, the need to include the community and continue investigations that realistically translate research into community settings should not be. Thus, the AAP urges that a strong focus on community participation and outreach be maintained and be a required component of the research portfolio for Centers.

Clarification Is Needed In Certain Areas

In a number of areas, the review report was unclear on important details of the proposed revisions. The AAP has identified the following questions in need of clarification:

How does the panel define "basic research?" The report is unclear as to whether this term is being used in a very broad or narrower sense when recommending to refocus the Centers.

Would funding by non-NIH sources be acceptable as an Investigator-Initiated Funded Grant or would the investigators have to obtain R01/R21 funding? If other types of funding would be acceptable, it would be helpful for some examples to be listed.

Did the panel propose that Children's Centers be funded for 5 continuous years or must they apply annually? The proposal states that the Centers would be funded for "up to five years (renewable upon favorable review)" but that the application cycle would be "annual."

In conclusion, the American Academy of Pediatrics appreciates this opportunity to communicate its concerns regarding proposed changes to the Centers for Children's Environmental Health and Disease Research. Like NIEHS and EPA, the AAP wishes to see this program continue its highly successful work in the most effective manner possible. If the AAP may provide further information or otherwise be of assistance, please contact Cindy Pellegrini in the Washington, DC office at 202/347-8600. Once again, thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Jay E. Berkelhamer". The signature is written in a cursive, flowing style.

Jay E. Berkelhamer, MD, FAAP
President

JB:cp